REMARKS

Claims 70, 72, 74-85, 88 and 90-94 are pending. The remaining claims are either withdrawn from consideration or cancelled. No claims have been allowed.

The present invention provides a gamma irradiated sterilized therapeutic composition comprising microparticles comprising at least one polymer and at least one therapeutically active agent wherein said microparticles are gamma irradiated at a temperature of less than 5 C. to thereby provide microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature of 25 C and wherein said at least one polymer is poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA) and wherein said at least one therapeutically active agent is tazarotene.

The Examiner has rejected all of the claims, under 35 USC 112, first paragraph, for lack of enablement. The rejection is overcome by this amendment which now limits the claims to the Examples as suggested by the Examiner. (Note that the claims include PLA as the polymer, well as the exemplified PLGA, However since PLGA includes the same monomer, i.e. lactic acid, that is included, along with glycolic acid, in the copolymer PGLA, it believed that it may be claimed without rejection under 35 USC 112 for lack of enablement.)

The Examiner has separately rejected claim 96 under 35 USC 112, but this claim has now been cancelled.

The Examiner has rejected all of the claims, except for the claims which are specific as to the therapeutically active agent being tazarotene, under 35 USC 102 for lack of novelty over Montari.

It is believed that the present amendment overcomes these rejections by limiting the claimed sterilized therapeutic compositions to those prepared by gamma irradiating at a

temperature of less than 5 C. to thereby provide microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature of 25 C. Furthermore, as claimed, said polymer is poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA) and said therapeutically active agent is tazarotene. It is this discovery that gamma irradiating a composition comprising microparticles comprising poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA) and tazarotene at a temperature of less than 5 C. results in the preparation of microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature of 25 C.

The above references cited by the Examiner do not recognize this phenomena, explicitly, nor do these references inherently carry out the sterilization with gamma radiation at the claimed temperature. Therefore the rejection under 35 USC 102 is incorrect for this reason, alone. Also, as the Examiner admits, Molinara does not disclose the use of tazarotene as the active agent. Indeed the Examiner has combined Molinara with other references to reject the claims to the tazarotene composition as obvious under 35 USC 103.

Nor is there any disclosure in said other references that would suggest the discovery made and claimed in the present claims, i.e. that gamma irradiating a composition comprising microparticles comprising poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA) and tazarotene at a temperature of less than 5 C. results in the preparation of microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature of 25 C. Therefore, there is no basis for making a rejection under 35 USC 103. That is, the presently amended claims are unobvious over the above reference. (In fact, the Examiner in his rejection for lack of enablement under 35 USC 112, first paragraph, admits, citing Montanari, that the irradiation of microspheres of PLA or PLGA polymers leads to unpredictable results. Also, the presence of a drug alters the effects of irradiation on the aggregation of microspheres of PLA or PLGA polymers. This

admission by the Examiner clearly supports the argument that the claims, as presently limited to a method of making a gamma irradiated sterilized therapeutic composition comprising microparticles of a poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA) polymer and tazarotene is unobvious.

It is believed that the claims, as presently amended, are patentable over the prior art. Applicants hereby request that the Examiner withdraw the outstanding rejection and pass the claims, as amended, to issue.

The undersigned is an attorney of record.

Date: January 5, 2009

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